Nguyet Phan
01/02/04 07:02 AM

To: NCIC HPV
cc:
Subject: Test Plan and Robust Summary Submission

201-15024

Nguyet Phan
ASRC Aerospace
OPPT Docket
EPA Docket Center

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Richard Henrich
<rhenrich@glcc.com>
12/31/03 05:37 PM

To: Rtk Chem@EPA, NCIC OPPT@EPA
cc:
Subject: Test Plan and Robust Summary Submission

Great Lakes Chemical Corporation (GLCC) and Albemarle Corporation are pleased to submit, attached below, the Robust Summary as part of the HPV Challenge Program for the following chemical:

1,3 Isobenzofurandione, 4,5,6,7- tetrabromo - CAS # 632-79-1

In addition GLCC and Albemarle are requesting a 30 day extension for the submission of the Data Summary and Test Plan for this chemical. GLCC and Albemarle plan to submit the Test Plan by the end of January 2004.

Please feel free to contact me (765-497-6114) with any questions you might have concerning this submission.

Sincerely,

Richard Henrich
Manager, Corporate Regulatory Affairs
Great Lakes Chemical Corp.
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Weat Lafayette, IN 47996
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201-15024

I U C L I D

Data Set

Existing Chemical	:	ID: 632-79-1
CAS No.	:	632-79-1
CAS Name	:	1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- (9Cl)
Product name	:	FireMaster PHT4

Producer related part

Company	:	GREAT LAKES CHEMICAL CORPORATION
Creation date	:	19.06.2003

Substance related part

Company	:	GREAT LAKES CHEMICAL CORPORATION
Creation date	:	19.06.2003
Status	:	
Memo	:	
Printing date	:	18.12.2003
Revision date	:	
Date of last update	:	18.12.2003
Number of pages	:	25
Chapter (profile)	:	Chapter: 1.0.1, 1.2, 1.6.1, 1.6.2, 1.8.1, 1.8.3, 1.8.4, 1.8.5, 1.10, 1.11, 2, 3, 4, 5, 7
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 APPLICANT AND COMPANY INFORMATION

1.2 SYNONYMS AND TRADENAMES

1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-

24.10.2003

Bromophthal

24.10.2003

PHT4

24.10.2003

Tetrabromophthalic anhydride

24.10.2003

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

2.1 MELTING POINT

Value : = 279.5 - 280.5 °C

24.10.2003 (27)

2.2 BOILING POINT

2.3 DENSITY

Type : relative density
Value : = 2.87 at °C

24.10.2003 (16)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

2.5 PARTITION COEFFICIENT

Method :
Year :
GLP : no data
Test substance : other TS: PHT-4

Method : Partition coefficient was determined using a 1,2-dichlorobenzene/water system. Two concentrations for each compound were studied using radiocarbon labeled compounds.
Result : The average partition coefficient (mean of two tests run in duplicate) for PHT-4 was 96.
Reliability : (2) valid with restrictions
18.12.2003 (31)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in :
Value : = 241 other: ppm at 25 °C
pH value :
concentration : at °C
Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description :
Stable :
Deg. product :
Method :
Year :
GLP : no data
Test substance : other TS: PHT-4

Method	:	Excess amounts of 14-C labeled compounds in distilled water was shaken in water bath at 35 C overnight. After centrifugation at 15, 25 or 35 C and at 12,000 x G for 1 hour, water solubility was determined by radioassay.
Result	:	The average solubility (ppm) for PHT-4 was 149, 241, and 242 at 15, 25 and 35 C.
Reliability	:	(3) invalid

18.12.2003 (32)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	other: silica gel surfaces
Light source	:	other: UV light
Light spectrum	:	nm
Relative intensity	:	based on intensity of sunlight
Deg. product	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: PHT-4.
Method	:	14-C-PHT-4 was applied to silica gel surfaces and then irradiated with UV light.
Result	:	PHT-4 was rapidly hydrolyzed (half-life <5 min) to tetrabromophthalic acid; and the later compound was then gradually and extensively photodegraded. The half-life of tetrabromophthalic acid was estimated to be about 5 hr. Ten degradation products were detected by TLC analysis. All of the degradation products appeared to be transitory. The transitory degradation products reached a maximum after about 1-2 days of UV irradiation and then gradually decreased upon further irradiation to yield more polar products and volatile materials.
Reliability	:	(2) valid with restrictions

18.12.2003 (33)

3.1.2 STABILITY IN WATER

3.1.3 STABILITY IN SOIL

Type	:	laboratory
Radiolabel	:	
Concentration	:	10 mg/kg
Soil temperature	:	28 °C
Soil humidity	:	
Soil classification	:	
Year	:	
Deg. product	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: tetrabromophthalic anhydride (PHT-4), lot #8225B, 0.15% H2SO4), technical grade and 14-C-labeled PHT-4 (Midwest Res. Inst, sp. act. 11.6 mCi/mM).
Method	:	Samples (432 g) of Monongahela sandy clay loam were premoistened and treated with test solutions (25 ml of the 160 ug/ml suspension of 14-C-PHT-4 in 10% acetone plus 2.5 ml distilled water or 2.5 ml of the 160 ug/ml suspension). Treated soil was mixed and divided into three flasks. Control group contained only acetone. Flasks were stoppered and incubated at 28 C and 70% relative humidity. They were sampled at 0, 1, 2, 4, 7, 14 and 28 days. Samples were combusted and counted.
Result	:	PHT-4 was repidly hudrolyzed to PHT-4 acid. Little volatilization of PHT-4 was observed and a large proportion (24 to 32%) of the radioactivity became soil bound after 28 days. The soil bound radiocarbon was identified as PHT-4 acid (94%) and PHT-4 (4.0%). This study indicates that PHT-4 would probably be persistent in soil.

Reliability : (2) valid with restrictions
18.12.2003 (2)

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	28 day(s) at °C
Concentration	:	.0098 mg/l
Elimination	:	yes
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 14-C-FireMaster, PHT-4, (ring-labeled, sp. act. 11.6 mCi/mmole) and non-labeled FireMaster to give a final sp. act. of 2.32 mCi/mmole.
Method	:	The bluegill sunfish, Lepomis macrochirus, was exposed to tetrabromophthalic anhydride (FireMaster PHT4) in a flow-through bioassay system. The compound was labeled with 14-C in the aromatic ring. Exposure was for 28 days at 0.0098 ppm followed by a 14 day withdrawal phase. Samples of water and both edible tissue and viscera of the fish were collected.
Remark	:	Sponsor: Velsicol Chemical Corp.
Result	:	Tetrabromophthalic anhydride was not accumulated by the bluegill sunfish at any time during the treatment phase. The limit of detection was 0.01 ppm for both edible and visceral tissue.
Reliability	:	(3) invalid

18.12.2003 (15)

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	static
Species	:	Salmo gairdneri (Fish, estuary, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
NOEC	:	= 1 measured/nominal
LC50	:	> 10 measured/nominal
Limit test	:	
Analytical monitoring	:	no data
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FireMaster, PHT-4, lot 6332-B.
Method	:	Five concentrations of PHT4, a control and solvent control were used with four replicates. Due to solubility the highest concentration obtainable was 10 mg/l. The toxicant was introduced into a glass jar containing water, mixed and 10 organisms (4 months old) were added. Flasks were incubated at 12 C for 96 hours.
Remark	:	Sponsor: Velsicol Chemical Corp.
Result	:	During the test the pH ranged from 6.77 to 7.28; dissolved oxygen ranged from 7.4 to 8.9 mg/l; temperature was 12.0 +/-0.5 C. The 96 hour LC50 for FireMaster, PHT4 to rainbow trout is >10.0 mg/l. Behavioral observations during the test indicated that rainbow trout exposed to concentrations of 1.8 mg/l were irritated with abnormal sounding behavior. Trout in the 5.6 and 10.0 mg/l concentrations were irritated with abnormal surfacing behavior and erratic swimming.
Reliability	:	(2) valid with restrictions

18.12.2003 (5)

Type	:	static
Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
NOEC	:	= 1
LC50	:	> 10 measured/nominal
Limit test	:	
Analytical monitoring	:	no data
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: Firemaster, PHT4, lot #6332-B.
Method	:	The bluegill sunfish, Lepomis macrochirus, was exposed to five concentrations of the test material in glass culture vessels for 96 hours.
Remark	:	Sponsor: Velsicol Chemical Corp.
Result	:	During the study the temperature was 22 +/- 0.5 C; dissolved oxygen was 1.7 to 8.7 mg/l; and pH was 6.39 to 7.39. Behavioral observations during the test indicated that bluegill sunfish exposed to concentrations of 1.8 and 3.2 mg/l became quiescent and irritated. Fish in the 5.6 and 10 mg/l concentrations became irritated and exhibited erratic swimming and abnormal surfacing behavior with gulping air at the surface. The 96 hour LC50 for Firemaster to bluegill sunfish is >10.0 mg/l.
Reliability	:	(2) valid with restrictions

18.12.2003 (4)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	µg/l
NOEC	:	= 5.6 measured/nominal
LC50	:	> 5.6 measured/nominal
Analytical monitoring	:	no data
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FireMaster PHT-4, lot #6332-B.
Method	:	Five concentrations of PHT4, a control and solvent control were used with four replicates. Due to solubility the highest concentration obtainable was 5.6 ppm. The toxicant was introduced into a flask containing water, mixed and 5 organisms (newly released instars) were added. Flasks were incubated at 17 C for 48 hours.
Remark	:	Sponsor: Velsicol Chemical Corp.
Result	:	Dissolved oxygen and pH were monitored during the stu dy but the table of values was not included in the copy of the report in the file. Temperature is listed as 17.5 C and pH as 7.31. The 48 hour LC50 for FireMaster PHT4 to D. magna is greater than 5.6 mg/l. The NOEL was 5.6 mg/l.
Reliability	:	(2) valid with restrictions

18.12.2003 (14)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type	:	soil
Species	:	aerobic microorganisms
Exposure period	:	28 day(s)
Unit	:	mg/kg soil dw
Analytical monitoring	:	no data
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: tetrabromophthalic anhydride (PHT-4), lot #8225B, 0.15% H2SO4), technical grade and 14-C-labeled PHT-4 (Midwest Res. Inst, sp. act. 11.6 mCi/mM).
Method	:	Samples (432 g) of Monongahela sandy clay loam were premoistened and treated with test solutions (25 ml of the 160 ug/ml suspension in 10% acetone plus 2.5 ml distilled water or 2.5 ml of the 160 ug/ml suspension). Treated soil was mixed and divided into three flasks. A control group contained only acetone. Flasks were stoppered and incubated at 28 C and 70% relative humidity. They were sampled at 0, 1, 2, 4, 7, 14 and 28 days. Bacteria and fungi were plated and counted.
Result	:	PHT-4 had a slight positive effect on the soil bacterial population at 10 ug/g but not at 1 ug/g and the soil fungal population was not affected at either level.
Reliability	:	(2) valid with restrictions

18.12.2003 (3)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	> 10000 mg/kg bw
Species	:	mouse
Strain	:	other: Charles River CD-1
Sex	:	male/female
Number of animals	:	10
Vehicle	:	other: corn oil
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FireMaster, PHT-4, lot 8424-B.
Method	:	Five male and 5 female mice were administered the test material (suspension in corn oil) as a single gavage dose of 10,000 mg/kg body weight. Animals were observed for toxicity for 14 days.
Remark	:	Sponsor: Velsicol Chemical Corp.
Result	:	No animals died during the study and all appeared normal. There were no gross lesions noted at necropsy. The minimum lethal dose by the oral route of administration was greater than 10,000 mg/kg body weight.
Reliability	:	(2) valid with restrictions

18.12.2003 (6)

Type	:	LD50
Value	:	> 50 mg/kg bw
Species	:	rat
Strain	:	other: Holtznan
Sex	:	no data
Number of animals	:	10
Vehicle	:	water
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: Tetrabromophthalic anhydride.
Method	:	Ten rats (Holtznan) were administered a single dose (gavage) of tetrabromophthalic anhydride in water. The dose administered was 10 ml/kg of a 5 mg/ml solution (50 mg/kg). Animals were observed for 14 days for signs of toxicity.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	No animals died during the study. The LD50 is greater than 50 mg/kg body weight.
Reliability	:	(2) valid with restrictions

18.12.2003 (30)

Type	:	LD50
Value	:	> 10000 mg/kg bw
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male
Number of animals	:	30

Vehicle	:	water
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: Tetrabromophthalic anhydride, ISO 5756, lot 149.
Method	:	Test material (50% weight/volume suspension in water) was administered by gavage to 6 groups of 5 male rats at doses of 0.215, 0.464, 1.00, 2.15, 4.64 and 10.0 gm/kg body weight. Animals were observed for signs of toxicity for 14 days.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	One death occurred which was attributed to accidental misplacement of the dose. The acute oral LD50 of tetrabromophthalic anhydride for male rats was greater than 10 gm/kg body weight.
Reliability	:	(2) valid with restrictions

18.12.2003 (9)

Type	:	LD50
Value	:	> 3200 mg/kg bw
Species	:	rat
Strain	:	no data
Sex	:	no data
Number of animals	:	
Vehicle	:	no data
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Reliability	:	(2) valid with restrictions

18.12.2003 (17)

5.1.2 ACUTE INHALATION TOXICITY

Type	:	LC50
Value	:	> 10.92 mg/l
Species	:	rat
Strain	:	other: Spartan
Sex	:	male/female
Number of animals	:	10
Vehicle	:	
Doses	:	
Exposure time	:	4 hour(s)
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: HIPS Resin/PHT4/Sb2O3, lot #853-11-3.
Method	:	Five male and five female rats (Spartan) were exposed to an atmosphere containing pyrolysis products of HIPS Resin/PHT4/Sb2O3 for 4 hours. Animals were observed for a period of 14 days and then sacrificed and necropsied. Pyrolysis products were produced by heating the test material to 492 to 512 C and passing the products directly into the exposure chamber.
Remark	:	Sponsor: Michigan Chemical Corp.

Result	:	All rats survived the exposure and the subsequent observation period. Signs during exposure included decreased motor activity, eye squint, and lacrimation. At 24 and 48 hours, decreased motor activity was observed. In addition, soft stool was exhibited by one rat at 48 hours. At 48 hours to termination, all rats appeared normal, except for two with soft stool. No gross lesions were observed at terminal necropsy that could be attributed to treatment.
Reliability	:	(2) valid with restrictions

18.12.2003 (19)

Type	:	LC50
Value	:	
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	6
Vehicle	:	
Doses	:	
Exposure time	:	30 minute(s)
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: pyrolysis products of Polyester D (tetrabromophthalic anhydride based polyester (12% Br), plus 5phr Sb_2O_3, 42% styrene, 25.9% glass.
Method	:	Three male and 3 female rats were placed in an exercise cylinder. The cylinder was set in motion and the heating element warmed. The sample of test material was placed on the element and the combustion gases were passed into the cylinder. Exposure was for 20 minutes.
Remark	:	Sponsor: Velsicol Chemical Corp.
Result	:	No incapacitation occurred during exposure but some slight loss of control from 12:00 on. Total mortality - 0/6. Necropsy of survivors revealed one animal with normal lungs, 4 animals with some slight hemorrhaging with a spot of necrotic tissue.
Reliability	:	(3) invalid Six animals were in the group, but only 5 are accounted. There is no information on the time between termination of exposure and necropsy. Details on the procedure are very sketchy.

18.12.2003 (10)

Type	:	LC50
Value	:	
Species	:	rat
Strain	:	other: Spartan
Sex	:	male/female
Number of animals	:	10
Vehicle	:	
Doses	:	
Exposure time	:	6 hour(s)
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: pyrolysis products of HIPS Resin/PHT4/Sb_2O_3.
Method	:	Five male and five female rats (Spartan) were exposed to an atmosphere containing pyrolysis products of HIPS Resin/PHT4/Sb_2O_3 for 6 hours. Animals were observed for a period of 14 days and then sacrificed and necropsied. Pyrolysis products were produced by heating the test material to 490 to 520 C and passing the products directly into the exposure chamber.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	All rats survived the exposure and the subsequent observation period.

Signs during exposure included eye squint, lacrimation, salivation, slight dyspnea and a a white deposit around the nares. At termination of exposure, two rats exhibited nasal prophyrin discharge. At 24-72 hours, eye squint and clear ocular discharge were observed, one rat exhibited tachypnea. At 4 days, eye squint was observed in 2 rats. From 5 days to termination, most rats appeared normal.
No gross lesions were observed at terminal necropsy that could be attributed to treatment.

Reliability : (4) not assignable
18.12.2003 (20)

Type : LC50
Value :
Species : rat
Strain : other: Spartan
Sex : male/female
Number of animals : 10
Vehicle :
Doses :
Exposure time : 4 hour(s)
Method :
Year :
GLP : no data
Test substance : other TS: HIPS Resin/Sb2O3, lot #853-11-1.

Method : Five male and five female rats (Spartan) were exposed to an atmosphere containing pyrolysis products of HIPS Resin/Sb2O3 for 4 hours. Animals were observed for a period of 14 days and then sacrificed and necropsied. Pyrolysis products were produced by heating the test material to 450 to 458 C and passing the products directly into the exposure chamber.
Remark : Sponsor: Michigan Chemical Corp.
Result : All rats survived the exposure and the subsequent observation period. Signs during exposure included eye squint, lacrimation, salivation, slight dyspnea and lacrimation. At 24 hours and to termination, most rats appeared normal. Sings observed included slight dyspnea in one rat at 24 hours and through 4 days; and soft stool in a few rats from 3 through 7 days and by several rats from 9 through 14 days.
Necropsy findings revealed 7 of 10 rats showing congestion of the lungs and one rat which exhibited petechiation of the lungs.

Reliability : (4) not assignable
18.12.2003 (21)

Type : LC50
Value : > 10.92 mg/l
Species : rat
Strain : other: Spartan
Sex : male/female
Number of animals : 10
Vehicle : other: none
Doses :
Exposure time : 4 hour(s)
Method :
Year :
GLP : no data
Test substance : other TS: FM PHT4 (micronized), lot 6332-B.

Method : Five male and five female rats (Spartan) were exposed to an atmosphere containing FM PHT-4 for 4 hours. Animals were observed for a period of 14 days and then sacrificed and necropsied. The calculated atmospheric concentration administered was approximately 10.92 mg/l.
Remark : Sponsor: Michigan Chemical Corp.
Result : All rats survived the exposure and the subsequent observation period.

Signs during exposure included decreased motor activity, eye squint, slight dyspnea and erythema.
No gross lesions were observed at terminal necropsy that could be attributed to treatment.
The acute inhalation toxicity of FM PHT4 (micronized), lot #6332-B would be greater than 10.92 mg/l.

Reliability : (2) valid with restrictions
18.12.2003 (18)

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD50
Value	:	> 10000 mg/kg bw
Species	:	rabbit
Strain	:	no data
Sex	:	no data
Number of animals	:	16
Vehicle	:	water
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FireMaster, PHT-4, lot 8424-B.

Method : Test material (moistened with water) was applied to the clipped skin on the backs of 4 groups of 4 rabbits at doses of 1.00, 2.15, 4.64 and 10.0 gm/kg body weight. The sites were covered with rubber dental dam and wrapped with gauze and adhesive tape. Twenty four hours later the bandages were removed and material removed by sponging. Animals were observed for signs of toxicity for 14 days.

Remark : Sponsor: Michigan Chemical Corp.

Result : Between the 10th and 14th days four rabbits died. One from each group, 1.00 and 4.64 g/kg and two from the 2.15 gm/kg group. Death in each rabbit was preceeded by diarrhea and the deaths were attributed to enteritis, a common syndrome in laboratory rabbits.
The acute dermal LD50 of tetrabromophthalic anhydride for rabbits was greater than 10 g/kg body weight. A single application of the moistened material produced no gross evidence of dermal irritation.

Reliability : (2) valid with restrictions
18.12.2003 (9)

Type	:	LD50
Value	:	> 200 mg/kg bw
Species	:	rabbit
Strain	:	no data
Sex	:	female
Number of animals	:	10
Vehicle	:	no data
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: Tetrabromophthalic anhydride.

Method : Test material on gauze patches was applied to the clipped skin on the backs of 10 female rabbits at 200 mg/kg body weight. The sites were secured with adhesive tape. Twenty four hours later the bandages were removed and material removed by sponging. Animals were observed for signs of toxicity for 48 hours.

Remark : Sponsor: Michigan Chemical Corp.

Result	:	None of the animals died during the study. When the patches were removed (24 hours) none of the animals showed any signs of any erythema or edema resulting from exposure to the test material. The dermal LD50 is greater than 200 mg/kg body weight in female rabbits.
Reliability	:	(2) valid with restrictions

18.12.2003 (29)

Type	:	LD50
Value	:	> 1000 mg/kg bw
Species	:	guinea pig
Strain	:	no data
Sex	:	no data
Number of animals	:	
Vehicle	:	no data
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Reliability	:	(3) invalid

18.12.2003 (17)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

Species	:	rabbit
Concentration	:	undiluted
Exposure	:	Occlusive
Exposure time	:	24 hour(s)
Number of animals	:	6
Vehicle	:	
PDII	:	.1
Result	:	not irritating
Classification	:	not irritating
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FM PHT4 (micronized), lot #6332-B.
Method	:	The test material (500 mg) was applied to the clipped skin on the backs of 3 male and 3 female rabbits. The sites on three animals were intact and on three were abraded. Sites were wrapped with gauze and occluded with Saran Wrap. Twenty-four hours later the bandages were removed and the sites washed with tepid water.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	Very slight erythema was noted on one animal (abraded); all other sites exhibited no evidence of erythema or edema. The primary ittitation score was 0.2 and the test material would not be considered a primary skin irritant.
Reliability	:	(2) valid with restrictions

18.12.2003 (24)

Species	:	other: No data

Concentration	:	undiluted
Exposure	:	Occlusive
Exposure time	:	24 hour(s)
Number of animals	:	
Vehicle	:	
PDII	:	
Result	:	not irritating
Classification	:	not irritating
Method	:	
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Conclusion	:	When applied to the intact abdominal skin under a binder of rubber dental damming for 24 hours at levels ranging from 1.00 to 10.0 g/kg (2.16-21.6 mmol/kg) body weight, no signs of dermal irritation occurred. During the exposure period, the animals at the highest level showed depressed righting and placement reflexes. Afterward, they appeared normal.
Reliability	:	(3) invalid

18.12.2003 (8)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	undiluted
Dose	:	100 other: mg
Exposure time	:	
Comment	:	not rinsed
Number of animals	:	6
Vehicle	:	
Result	:	irritating
Classification	:	irritating
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FM PHT4 (micronized), lot #6332-B.
Method	:	The test material (100 mg) was instilled into the conjunctival sac of the right eye of each of 3 male and 3 female rabbits. Eyes were scored for irritation at 24, 48 and 72 hours and at 7 days.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	Examination at 72 hours did not reveal corneal damage in any of the rabbits. FM PHT4 (micronmize) was considered an eye irritant.
Reliability	:	(2) valid with restrictions

18.12.2003 (23)

Species	:	rabbit
Concentration	:	undiluted
Dose	:	100 other: mg
Exposure time	:	72 hour(s)
Comment	:	
Number of animals	:	6
Vehicle	:	
Result	:	not irritating
Classification	:	not irritating
Method	:	
Year	:	

GLP	:	no data
Test substance	:	
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Conclusion	:	Using the same test system as Wazeter and Goldenthal, 1974, the chemical was not found to be an eye irritant.
Reliability	:	(3) invalid

18.12.2003 (13)

5.3 SENSITIZATION

Type	:	no data
Species	:	guinea pig
Concentration	:	1st.: Induction .1 % other: intradermal 2nd.: Challenge .1 % other: intradermal 3rd.:
Number of animals	:	12
Vehicle	:	physiol. saline
Result	:	sensitizing
Classification	:	sensitizing
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FM PHT4 (micronized), lot #6332-B.
Method	:	The test material (0.1% in 0.9% sodium chloride) was injected intradermally into the back and flanks of guinea pigs. The control and test compound were injected 3x/week for a total of 10 sensitizing doses. The first sensitizing dose was 0.05 ml and the remaining nine were 0.10 ml. Two weeks following the administration of the tenth dose, a challenge dose, at a volume of 0.05 ml was given intradermally. Reactions to the challenge were scored.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	All eight guinea pigs responded to the challenge dose. Four exhibited an average flare response which was greater than twice the average response obtained in the sensitizing doses. The remaining four animals exhibited responses which were approximately 158 to 186% of the average response obtained during the sensitizing period. No significant effect was noted in the wheal response.
Reliability	:	(2) valid with restrictions

18.12.2003 (22)

Type	:	no data
Species	:	guinea pig
Concentration	:	1st.: Induction 95 % occlusive epicutaneous 2nd.: Challenge 50 % occlusive epicutaneous 3rd.: Challenge 5 % occlusive epicutaneous
Number of animals	:	20
Vehicle	:	other: acetone
Result	:	sensitizing
Classification	:	sensitizing
Method	:	
Year	:	
GLP	:	no data
Test substance	:	no data
Method	:	Test material as 95% w/v formulation in a cetone for 6 hours once per week for a total of 3 applications as patches occluded with dental dam.

		Primary challenge: test material as 50% w/v formulation in acetone for 6 hours 2 weeks later. Rechallenge: test material as a 5.0% w/v foumulation in acetone for 6 hours 1 week later.
Result	:	Primary challenge: slight patchy eryth (sic) and slight patchy erythema and cases of confluent or moderate patchy erythema The same results were found in the rechallenge experiment.
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Reliability	:	(3) invalid

18.12.2003 (12)

Type	:	no data
Species	:	guinea pig
Number of animals	:	3
Vehicle	:	
Result	:	not sensitizing
Classification	:	not sensitizing
Method	:	
Year	:	
GLP	:	no data
Test substance	:	no data
Result	:	In three guinea pigs administered 0.25-1.0 g/kg (0.54-2.2 mmol/kg) of a solid form via cuff, slight edema and erythema resulted in 24 hours, while peeling was observed for up to two weeks. When tested as 1% solution in acetone, dioxane, and guinea pig fat in 5 animals, tetrabromophthalic anhydride was found to not be a skin sensitizer.
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Reliability	:	(3) invalid

18.12.2003 (17)

5.4 REPEATED DOSE TOXICITY

Type	:	
Species	:	rat
Sex	:	male/female
Strain	:	other: Spartan
Route of admin.	:	inhalation
Exposure period	:	3 weeks
Frequency of treatm.	:	4 hr/day, 5 days/week
Post exposure period	:	
Doses	:	2 and 8 mg/l
Control group	:	yes, concurrent vehicle
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FM PHT4 (micronized), lot #6332-B.
Method	:	Three groups of 3 male and 3 female rats were used for the study. Addition of the test compound to the chamber atmosphere was controlled by a Wright Dust Feeder. The groups were exposed to a) air flow only, b) 2 mg/k test material or c) 8 mg/l test material. Exposures were for 4 hours daily, 5 days/week for three weeks.

Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	Clinical observations in the treated groups included salivation, lacrimation, nasal discharge and nasal prophyrin discharge. Respiratory congestion was observed once only in one animal at 8 mg/l. No deaths occurred. Changes in body weights were observed in the treated male and female rats following 3 weeks. Treated animals exhibited slightly less body weight gains than did controls. Food consumption was slightly less for treated females than for controls. Hematological, biochemical and urinalysis data at 20 days did not exhibit any changes that were compound related. Bromine analysis of selected tissues and blood by neutron activation revealed increased bromine values in the tissues and blood in animals at 8 mg/l as compared to controls. No compound related gross patholgic lesions were seen at necropsy in the treated groups. Decreases in liver weight and increases in lung weight at both exposure levels were considered compound effects. An increase in relative adrenal and thyroi d weight in females at the 8 mg/l dose may have been treatment related. Microscopically, an increase in inflammatory lung lesions in both treatments may have been compound related.
Reliability	:	(2) valid with restrictions
18.12.2003		(25)

Type	:	
Species	:	rabbit
Sex	:	male
Strain	:	New Zealand white
Route of admin.	:	dermal
Exposure period	:	4 weeks
Frequency of treatm.	:	5 days/week
Post exposure period	:	
Doses	:	50, 500 and 5000 mg/kg/day
Control group	:	yes, concurrent vehicle
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: FM PHT4 (micronized), lot #6332-B.
Method	:	Test material was applied dermally at dosages of 50, 500 and 5000 mg/kg/day for 5 days/week for 4 weeks to the clipped backs of groups of 3 male and 3 female rabbits. An additional group served as the control. The test material was moistened to a paste with saline and applied to the skin. Controls received saline only. Animals were held in stocks for the 6 hour administration period, then washed and returned to cages.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	All animals at 5000 died or were sacrificed in extremis. These animals showed losses in body weight prior to death. Very slight to slight and occasionally moderate erythema was noted for controls and rabbits at 50 mg/kg. Very slight to moderate erythema was noted at 500 and 5000 mg/kg. Moderate desquamation was noted for 3 animals at 5000. At 14 days one rabbit at 5000 mg/kg showed a moderate increase in urea nitrogen. At 26 days the surviving rabbit at 5000 showed a neutrophilia with a lymphopenia, nucleated erythrocytes, marked increases in glucose and urea nitrogen and albumin in the urine. In the animals at 5000 mg/kg, pale liver, accentuated liver lobulation and gastric irritation in several animals may have been compound related. Microscopically, the only lesion in animals from 50 or 500 mg/kg which was considered compound related was very slight hyperkeratosis of the application site in one rabbit at 500 mg/kg. The NOAEL was 50 mg/kg/day.
Reliability	:	(2) valid with restrictions
18.12.2003		(26)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Bacterial gene mutation assay
System of testing	:	Salmonella (5 strains) and Saccharomyces (D4)
Test concentration	:	0.05, 0.25, 0.5, 5, 50 ug/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: 859-74-4, FM PHT4.
Method	:	The test material was evaluated for mutagenicity in Salmonel la (5 strains) and Saccharomyces (D4) in the presence and absence of a metabolizing enzyme fraction.
Remark	:	Sponsor: Michigan Chemical Corp.
Result	:	The test material was negative in all assays.
Reliability	:	(2) valid with restrictions

18.12.2003 (1)

Type	:	Bacterial gene mutation assay
System of testing	:	Salmonella typhimurium (TA98, TA100, TA1535, TA1537)
Test concentration	:	10, 100, 1000 and 10,000 ug/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Reliability	:	(3) invalid

18.12.2003

Type	:	Bacterial gene mutation assay
System of testing	:	Salmonella typhimurium (TA98, TA100, TA1535, TA1537 and TA1538)
Test concentration	:	0.1, 1.0, 10, 100 and 1000 ug/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Reliability	:	(3) invalid

18.12.2003

Type	:	Bacterial gene mutation assay
System of testing	:	Salmonella typhimurim (TA98, TA100, TA1535 and TA1537)
Test concentration	:	3, 10, 33, 100, 333, 1000, 3333, 6666 and 10,000 ug/plate
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	negative

Method	:	
Year	:	
GLP	:	no data
Test substance	:	no data
Source	:	Review of Toxicological Literature; Prepared for Scott Masten, Ph.D., National Institute of Environmental Health Sciences. Submitted by Raymond Tice, Ph.D., Integrated Laboratory Systems; October 1999.
Reliability	:	(3) invalid

18.12.2003

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female
Strain	:	other: Charles River CD
Route of admin.	:	gavage
Exposure period	:	Gestation day 6 through 15
Frequency of treatm.	:	daily
Duration of test	:	Gestation day 20
Doses	:	30, 100, 300, 1000, 3000, and 10,000 mg/kg/day
Control group	:	yes, concurrent vehicle
NOAEL maternal tox.	:	= 3000 mg/kg bw
NOAEL teratogen.	:	= 3000 mg/kg bw
Method	:	
Year	:	
GLP	:	no data
Test substance	:	other TS: Firemaster PHT-4 (Tetrabromophthalic anhydride), lot 8524-B.
Method	:	Firemaster PHT-4 was administered by gavage at doses of 30, 100, 300, 1000, 3000 and 10,000 mg/kg/day to groups of five pregnant rats from gestation day 6 through day 15. Control rats received the vehicle, 0.5% Methocel, at 25 ml/kg/day. Rats were sacrificed on gestation day 20 and the uterine contents examined.
Remark	:	Sponsor: Velsicol Chemical Corp.
Result	:	There were no changes in appearance or behavior which were treatment related for females receiving 3000 mg/kg/day or less. There were no compound related effects indicated by the number of viable or nonviable fetuses, resorptions, implantations and corpora lutea for females with dosages of 3000 mg/kg/day or less. Four of five females receiving 10,000 mg/kg/day were dead by gestation day 14, the fifth female was gravid at sacrifice. These deaths were attributed to treatment.
Reliability	:	(2) valid with restrictions

18.12.2003 (11)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

Type of experience : Human - Medical Data

Method : Fifty human test subjects were used in a repeated insult patch test. The test material, FireMaster(R) PHT4 was used as received. None induction patches of the test material were placed oneach subject. The series was followed 12 days later by a single challenge patch. The induction patches were applied on Mon, Wed and Thrs, allowed 24 hour contact and then scored. For the challenge patch, a new site was used adjacent to the induction site. The site was scored at 24 and 48 hours.

Remark : Sponsor: Michigan Chemical Corp.
Human repeated insult patch test with FireMaster(R) PHT4.

Result : None of the subjects exhibited any erythema or edema during the series of induction applications. There was no evidence of skin sensitization in any of the subjects following challenge patch application.

Reliability : (2) valid with restrictions
18.12.2003 (28)

5.11 ADDITIONAL REMARKS

Type : other: Pharmacokinetics of PHT-4 in rats.

Method : A single oral dose of PHT-4 was administered to male and female rats.

Result : PHT-4 was hydrolyzed to the acid form and partly absorbed in the gastrointestinal tract. The absorbed portion was readily eliminated in the urine (about 20%) within 24 hours and the unabsorbed portion was eliminated in the feces within 48 hours (about 75%). The ratioactivity in the urine consisted of 27% acid released PHT-4 acid, 27% water solubles and 45% of the radioactivity was lost upon acidification to pH 1.0. The radiocarbon in the feces consisted of 25% acid released PHT-4 acid, 20% unextractable solids and again 55% was lost upon acidification. There was no significant difference in the pharmacokinetics of PHT-4 between male and female rats. Total residues in all tissues amounted to <0.2% of the administered dose 2 days after treatment. Blood concentrations of PHT-4 equivalents peaked 2 hours after dosing 3.462 ppm then gradually decreased to 0.013 ppm after 72 hours. The portion of this compound absorbed by rats appeared to follow a one compartment open model system. The chemical was rapidly distributed in the body and the rate of elimination in urine was proportional to the concentration of the chemical in the blood. The rate constant for elimination (Ke) was 0.081 and the half life in blood was 8.5 hours. The absorbed radiocarbon (>20%) should neither be persistent nor accumulative since the maximum half life in any tissue is less than 7 hours. The extapolated maximum residues (plateau) could be reached within 2 days in a continuous feeding study of daily dosing.

Reliability : (2) valid with restrictions
18.12.2003 (7)

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

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